UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,517	01/16/2004	Mylavarapu Venkatramesh	16518.132	5271

28381 7590 05/05/2009

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
CARR, DEBORAH D	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,517	VENKATRAMESH ET AL.	
	Examiner	Art Unit	
	DEBORAH D. CARR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86,89-94 and 97-110* is/are pending in the application.

4a) Of the above claim(s) *89, 91-92 99-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86,90,93,94,97 and 98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The finality of the rejection of the last Office action has been withdrawn.

2. Applicant's arguments filed 12 November 2008, with respect to the rejections under 35 USC§102(b) have been fully considered but were not persuasive. The rejections of claims 86, 90, 93-94 have been maintained.

3. Claim 98 will be included in the rejection under 35 USC§102(b) in view of Fernholz et al.

4. Applicant's arguments filed 12 November 2008 regarding the rejection under 35 USC§101 have been fully considered and were persuasive. The rejections of claims 86, 90, 93-94, 97 and newly added claim 98 reading on the previously rejected claim 86 has been withdrawn.

5. The objection of claim 90 as a product-by-process claim has been withdrawn.

6. Claims 89, 91-92, 99-110 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. A new rejection is deemed proper under 35 USC§112, 2nd paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 86, 90, 93-94, 97-98 rejected under 35 U.S.C. 102(b) as being anticipated by Fernholz et al.

Fernholz et al. teaches an oil containing brassicasterol as one of its components. Claim 86 only requires that instant oil consist of a compound selected from the group consisting of brassicastanol, or its ester, stigmastanol, or it ester. Dependent claims 93-94 & 97 all add an additional compound such as campestanol, phytostanol, sitostanol or their deriviatives.

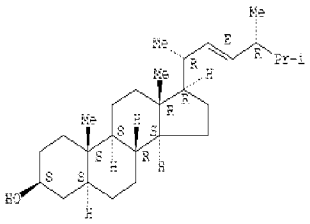
Applicants arguments have been taken into consideration be the claims list supra are still considered to be anticipated by Fernholz et al.

It was previously argued by the examiner that the instant compounds were conventionally known in the art as is their chemical structure and that there was no indication that the instant compounds were structurally different since applicants referred to them by their conventionally known names. Therefore Fernholz et al. would anticipate that if the compounds found in the prior art were the same compounds applicants was claiming.

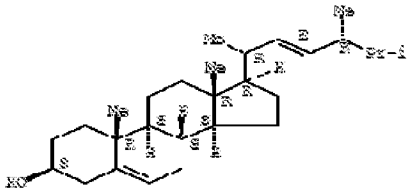
Applicant's then included the structure of their compound brassicastanol and stigmastanol into claim 86 to shown the C-22 double bond and to differentiate it from the stigmastanol that is taught by Fernholz et al. Then

applicants argued that no proof was given to show that either of Fernholz's brassicastanol or stigmastanol contains a double bond at position C-5 or C-22.

A structure search of Fernholz et al. disclosed the compounds contained in the reference and their chemical structures. The brassicastanol taught by Fernholz et al. has the following structure:



As seen in the structure supra, the compound taught by Fernholz et al. contains a double bond on the C-22 carbon. This is proof that during hydrogenation of brassicasterol,



The process only reduces the C-5 double bond leaving the C-22 double bond intact. Therefore the brassicastanol compound anticipates the instant invention.

Regarding claim 90, campesterol and its derivatives are present in a reduced level which is interpreted to read on zero. The source taught in Fernholz et al. does not have to contain these components thereby anticipating the instant invention.

Claims 93 & 94 are anticipated by Fernholz et al. by the presence of stigmastanol and its derivatives which are also know as sitostanol.

Applicant's final argument is that Fernholz et al. produces both brassicastanol and stigmastanol outside of the plant. As currently presented for prosecution, claim 86 does not require that the oil remains present in the plant or that the hydrogenation process occurs inside of the plant. Claim 86 just reads on oil containing these components and not on a seed that has been modification in such a way that hydrogenation occurs within the seed producing the oil containing brassicastanol or stigmastanol and its derivatives.

Claim 98 is a product-by-process claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior

product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical

comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Regarding claim 98, as seen supra Fernholz et al. teaches oil containing the one of the required components of the oil.

(New) Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 98 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 98 recites the limitation "oil is produced in a transgenic seed" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no indicating in claim 86 that the oil originates in a transgenic seed. As written the source of the oil is not limited to a seed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc